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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,323	11/26/2003	Enrico Alessi	64659-00003USPX	9467

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EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,323	ALESSI ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-17* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-8 and 13 -17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed December 17, 2007, have been fully considered and they are deemed to be persuasive. The following rejections are newly applied in light of newly discovered art. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1, 3-8 and 13 -17 are under examination.

Claims 9-12 are withdrawn as being drawn to a nonelected invention. The election was made with traverse.

Claim 2 is cancelled.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 3-7, and 13-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a

useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. See MPEP 2106.

The instant claims do not require a tangible final result. A tangible final result requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a method of identifying groups of co-regulated and co-expressed genes using clustering. Although the last step is a step of outputting in a selected data format, this step does not necessarily require a tangible result. For example, the selected data format could be a table that is stored in memory or in a carrier wave. In this instance the data is never communicated to the outside world and is not a tangible result. Thus, instant claims do not require a tangible final result. This rejection could be overcome by amendment of the claims to identify/recite a concrete result and to recite that the result is outputted to a display or to a user or outputted in a user readable format. However, applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Note:

This rejection was originally applied in the Office Action mailed March 21, 2007. The Applicants replied to this rejection by amending the claims to include an outputting step and the rejection was withdrawn in the Office Action mailed September 19, 2007. This rejection is now being reapplied, because of recent Court decisions suggesting that

a final result sent over a network or in the form of a carrier wave is not a tangible result. *See In re Nuijten*, CAFC, decided September 20, 2007.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3-7, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quackenbush (Nature Reviews Genetics (2001) Volume 2, pages 418-427) in view of Getz et al. (PNAS (2000) Volume 97, Number 22, pages 12079-12084) in view of Dougherty et al. (Journal of Computation Biology (January 2002) Volume 9, Number 1, pages 105-126) further in view of Tolley (US 2004/0128080).

The instant claims are drawn to a method of clustering wherein a dataset is clustered into smaller datasets, the smaller datasets are paired and subjected to filtering, characteristic parameters of the pairs are calculated, a value is generated as a function of the parameters, and pairs with values greater than a threshold are identified as network of genes and pairs with values lower than a threshold are discarded.

Regarding claims 1, 13, and 15-17, Quackenbush teaches a method where a dataset is clustered based on gene expression that varies (page 420, right column; page 422, right column); identifying subsets of genes that satisfy the clustering criterion (page 422, right column); applying a logic filtering criteria of the data in the dataset (defined in the specification as any logic criterion that a user may impose on the data. (See specification, page 8, paragraph 50), i.e. such as selecting only those genes with a twofold increase in differential expression) (page 420, right column); for each filtering criterion, generating a filtered data subsets (page 420, right column; page 422, right column); establishing pair combinations of gene subsets by said clustering and said filtering (i.e. selecting two clusters) (page 422, right column); generating for each pair combination a characteristic value in function of the characteristic parameters (i.e. determining the distance between clusters) (page 422, right column); identifying groups of genes associated with pair combinations whose characteristic value is greater than a certain pre-established threshold as members of a network (page 422).

However, Quackenbush does not teach discarding pair combinations of groups of genes whose characteristic value is smaller than a threshold.

Regarding claims 1, 13, and 15-17, Getz et al. teach a method of clustering wherein a dataset is clustered (page 12080, left column); and identifying pairs of datasets whose values is greater than a threshold as a network of genes and discarding pairs of datasets whose values are smaller than a threshold (abstract; page 12080-page 12081, left column, top).

However, neither Quackenbush nor Getz et al. disclose using a decision algorithm based on soft computing or wherein the datasets are presented in tables.

Regarding claims 1, 13, and 15-17, Tolley teaches using clustering algorithms on datasets that are presented in tables (page 7, paragraph 0059-0062; page 11, paragraph 0096) and outputting the results to a user selected format (page 7, paragraph 0054).

However, Quackenbush, Getz et al., or Tolley teach using a decision algorithm based on soft computing.

Regarding claims 1, 3, 13, and 15-17, Dougherty et al. teach that data may be clustered using a variety of soft computing techniques including fuzzy logic (abstract).

Regarding claim 4, Getz et al. also teach that the parameter is tied to gene expression levels (page 12082, left column).

Regarding claim 5, Tolley also teaches that the parameter is a correlation coefficient (page 1, paragraph 004).

Regarding claim 6, Getz et al. also teach that clusters with a low number of genes are eliminated (eliminating clusters that do not satisfy a size criterion) (page 12080, left column).

Regarding claim 7, Dougherty et al. disclose using SOM or K-means clustering (page 1118).

Regarding claim 7, Quackenbush teaches using agglomerative hierarchic algorithms (page 422, right column).

Regarding claim 14, Dougherty et al. teach training the fuzzy logic not using any online capabilities (page 124).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of Quackenbush, Getz et al., Dougherty et al. and Tolley to yield the predictable result of predicting gene network via known clustering methods. Quackenbush teaches known clustering methods that incorporate filtering and pairing gene subsets. Getz et al. teaches that their method may be used with any clustering algorithm (page 12079, left column, bottom). Dougherty et al. also teach known clustering methods where soft computing techniques are used to generate clusters (abstract). Tolley teaches that databases are typically organized in tables (page 7, paragraph 0057) which merely present the data in a particular format and does not effect function of the other methods. Each of these elements can be used in combination with all the other elements with no change in their respective functions, to yield the predictable result of predicting a gene network.

Withdrawn Rejections

6. Applicant's arguments, filed December 17, 2007, with respect to the rejection made under 35 U.S.C. §103 as being unpatentable over Getz et al., Dougherty et al.

and Tolley have been fully considered and are persuasive. The pair combinations of Getz et al. are not a pair combination of two datasets of genes. Rather, they are pair combination of a dataset of samples and a dataset of genes. This rejection has been withdrawn.

In addition, the rejections made under 35 U.S.C. §112 2nd paragraph have been withdrawn in view of the amendments filed December 17, 2007.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M- Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Examiner, Art Unit 1631
3/17/2008